Notice of Allowability	Application No. 10/017,168	Applicant(s) LIU ET AL.	
	Examiner Vanessa L. Ford	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *1/3/05, 3/13/05 & 4/19/05*.

2. ☒ The allowed claim(s) is/are *1-2, 4-16, 27-28 and 30-31. The claims have been renumbered as claims 1-19*.

3. ☒ The drawings filed on *14 December 2001* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *3/13/05&4/19/05* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

5-0-0

ALLOWANCE

1. This Office Action is responsive to Applicant's response January 3, 2005. All rejections of record are withdrawn in view of Applicant's amendment, remarks and attached Examiner's amendment. Claims 1-2, 4-16, 27-28 and 30-31 are allowed.

2. The following is an examiner's statement of reasons for allowance. The prior art cited neither teaches nor suggests a method of detecting the presence of *Treponema pallidum* or anti-treponemal antibodies in a biological sample, wherein the acidic repeat protein or the isolated immunogenic *Treponema pallidum* peptide(s) of the acidic repeat protein comprises the amino acid sequence set forth in SEQ ID NO: 2, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 20, 22, 24 or 26 and detecting formation of a complex between the immunogenic protein or peptide and the antibody, wherein the presence of the complex indicates the presence of *Treponema pallidum* or anti-treponemal antibodies in the biological sample. The closest prior art is Hunter et al *(Journal of Clinical Microbiological*, Sept. 1992, pages 483-486 and Norgard et al (Journal of Clinical Microbiological, October 1984,p. 711-717), which do not disclose or teach the claimed amino acid sequences.

Examiner's Amendment

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

A. Authorization for this examiner's amendment was given in a telephone interview with Debra Gordon and Tanya Harding on March 13, 2005 and April 19, 2005. Authorization was also given to cancel non-elected claims.

B. Amend the application as follows:

In the claims:

1. (**Currently amended**) A method of detecting the presence of *Treponema pallidum* or anti-treponemal antibodies in a biological sample, comprising: contacting an isolated *Treponema pallidum* acidic repeat protein or one or more isolated, immunogenic *Treponema pallidum* peptide(s) of the acidic repeat protein with an antibody-containing biological sample, wherein the acidic repeat protein or the isolated immunogenic *Treponema pallidum* peptide(s) of the acidic repeat protein comprises the amino acid sequence ~~EVEDX$_1$PX$_2$VVEPASX$_3$X$_4$EGGER, wherein X$_1$ is A or V; X$_2$ is K or G; X$_3$ is E or G; and X$_4$ is R or H~~set forth in SEQ ID NO: 2, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 20, 22, 24, or 26; and detecting formation of a complex between the immunogenic protein or peptide and the antibody, wherein the presence of the complex indicates the presence of *Treponema pallidum* or anti-treponemal antibodies in the biological sample.

2. (**Previously presented**) The method of claim 1, wherein the isolated, immunogenic *Treponema pallidum* peptide comprises a repeat region of the acidic repeat protein.

3. (**Cancelled**).

4. (**Currently amended**) The method of claim 1, wherein the ~~immunogenic peptide~~acidic repeat protein is encoded by a nucleotide sequence as shown in SEQ ID NOs: 1, 3, 5, 19, 21, 23, ~~and~~or 25.

5. (**Currently amended**) The method of claim 1, wherein the immunogenic peptide comprises ~~an~~the amino acid sequence having the sequence shown in SEQ ID NO: 15.

6. (**Original**) The method of claim 1, wherein the *Treponema pallidum* is *T. pallidum* subspecies *pallidum*, *T. pallidum* subspecies *pertenue* (CDC-2 strain), *T. pallidum* subspecies *pertenue* (CDC-1 strain), or *T. pallidum* subspecies *endemicum*.

7. (**Previously presented**) The method of claim 1, wherein detecting the presence of the complex indicates the presence of the disease syphilis, yaws, or bejel.

8. (**Currently amended**) The method of claim 1, wherein the immunogenic peptide comprises the amino acid sequence shown in SEQ ID NO: 2~~, or a conservative variation thereof~~, and wherein the presence of the complex indicates the presence of syphilis.

9. **(Currently amended)** The method of claim 1, wherein the immunogenic peptide comprises the amino acid sequence shown in SEQ ID NO: 4~~, or a conservative variation thereof~~, and wherein the presence of the complex indicates the presence of yaws.

10. **(Currently amended)** The method of claim 1, wherein the immunogenic peptide comprises the amino acid sequence shown in SEQ ID NO: 6~~, or a conservative variation thereof~~, and wherein the presence of the complex indicates the presence of bejel.

11. **(Previously presented)** The method of claim 1, wherein the acidic repeat protein or immunogenic peptide is bound to a solid phase.

12. **(Previously presented)** The method of claim 1, wherein the acidic repeat protein or immunogenic peptide is labeled.

13. **(Previously presented)** The method of claim 12, wherein the label comprises an electrochemiluminescent label, a chemiluminescent label, an enzymatic label, a bioluminescent label, or a fluorescent label.

14. **(Original)** The method of claim 1, further comprising incubating the peptide-antibody complex with a second antibody specific for the peptide, wherein the second antibody is labeled with a detectable label and binds to the peptide-antibody complex.

15. **(Original)** The method of claim 1, wherein the biological sample comprises wounds, blood, tissues, saliva, semen, vaginal secretions, tears, urine, bone, muscle, cartilage, CSF, skin, or any human tissue or bodily fluid.

16. **(Currently amended)** A method of detecting the presence of *Treponema pallidum* in a biological sample, comprising: contacting an isolated antibody specific for an immunogenic peptide of a *T. pallidum* acidic repeat protein with a biological sample, wherein the acidic repeat protein comprises the amino acid sequence ~~$EDX_4PX_2VVEPASX_3X_4EGGER$, wherein X_4 is A or V; X_2 is K or G; X_3 is E or G; and X_4 is R or H~~set forth in SEQ ID NO: 2, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 20, 22, 24, or 26; and

detecting formation of a complex between the acidic repeat protein or a peptide of the acidic repeat protein, if such is in the biological sample, and the antibody, wherein the presence of the complex indicates the presence of *Treponema pallidum*.

17-26. **(Cancelled)**.

27. (**Currently amended**) The method of claim 1, wherein the immunogenic peptide comprises ~~an~~the amino acid sequence as shown in SEQ ID NO: 20.

28. (**Previously presented**) A kit for detecting *T. pallidum* in a biological sample using the method of claim 1, comprising an isolated acidic repeat protein or one or more isolated, immunogenic *Treponema pallidum* peptide of the acidic repeat protein, and instructions for carrying out the method of claim 1.

29. (**Cancelled**).

30. (**Currently amended**) The method of claim 2, wherein the repeat region of the acidic repeat protein comprises ~~an~~the amino acid sequence ~~selected from any sequence comprising:~~

~~EVEDX$_4$PX$_2$VVEPASX$_3$X$_4$EGGEREVEDX$_4$PX$_2$VVEPASX$_3$X$_4$EGGER (wherein X$_4$ is A or V; X$_2$ is K or G; X$_3$ is E or G; and X$_4$ is R or H), which has an immunogenicity specific to *Treponema pallidum*~~set forth in SEQ ID NO: 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, or 18.

31. (**Previously presented**) The method of claim 16, wherein the immunogenic peptide comprises a repeat region of the acidic repeat protein.

32-36. (**Cancelled**).

4. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
May 5, 2005

NITA MINNIFIELD
PRIMARY EXAMINER
5/9/05

CLEAN COPY OF CLAIMS

1. A method of detecting the presence of *Treponema pallidum* or anti-treponemal antibodies in a biological sample, comprising: contacting an isolated *Treponema pallidum* acidic repeat protein or one or more isolated, immunogenic *Treponema pallidum* peptide(s) of the acidic repeat protein with an antibody-containing biological sample, wherein the acidic repeat protein or the isolated immunogenic *Treponema pallidum* peptide(s) of the acidic repeat protein comprises the amino acid sequence set forth in SEQ ID NO: 2, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 20, 22, 24 or 26 and detecting formation of a complex between the immunogenic protein or peptide and the antibody, wherein the presence of the complex indicates the presence of *Treponema pallidum* or anti-treponemal antibodies in the biological sample.

2. The method of claim 1, wherein the isolated, immunogenic *Treponema pallidum* peptide comprises a repeat region of the acidic repeat protein.

4. The method of claim 1, wherein the acidic repeat protein is encoded by a nucleotide sequence as shown in SEQ ID NO: 1, 3, 5, 19, 21, 23 or 25.

5. The method of claim 1, wherein the immunogenic peptide comprises the amino acid sequence having the sequence shown in SEQ ID NO: 15.

6. The method of claim 1, wherein the *Treponema pallidum* is *T. pallidum* subspecies *pallidum*, *T. pallidum* subspecies *pertenue* (CDC-2 strain), *T. pallidum* subspecies *pertenue* (CDC-1 strain), or *T. pallidum* subspecies *endemicum*.

7. The method of claim 1, wherein detecting the presence of the complex indicates the presence of the disease syphilis, yaws, or bejel.

8. The method of claim 1, wherein the immunogenic peptide comprises the amino acid sequence shown in SEQ ID NO: 2, and wherein the presence of the complex indicates the presence of syphilis.

9. The method of claim 1, wherein the immunogenic peptide comprises the amino acid sequence shown in SEQ ID NO: 4, and wherein the presence of the complex indicates the presence of yaws.

10. The method of claim 1, wherein the immunogenic peptide comprises the amino acid sequence shown in SEQ ID NO: 6, and wherein the presence of the complex indicates the presence of bejel.

11. The method of claim 1, wherein the acidic repeat protein or immunogenic peptide is bound to a solid phase.

12. The method of claim 1, wherein the acidic repeat protein or immunogenic peptide is labeled.

13. The method of claim 12, wherein the label comprises an electrochemiluminescent label, a chemiluminescent label, an enzymatic label, a bioluminescent label, or a fluorescent label.

14. The method of claim 1, further comprising incubating the peptide-antibody complex with a second antibody specific for the peptide, wherein the second antibody is labeled with a detectable label and binds to the peptide-antibody complex.

15. The method of claim 1, wherein the biological sample comprises wounds, blood, tissues, saliva, semen, vaginal secretions, tears, urine, bone, muscle, cartilage, CSF, skin, or any human tissue or bodily fluid.

16. A method of detecting the presence of *Treponema pallidum* in a biological sample, comprising:

contacting an isolated antibody specific for an immunogenic peptide of a *T. pallidum* acidic repeat protein with a biological sample, wherein the acidic repeat protein comprises the amino acid sequence set forth in SEQ ID NO: 2, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 20, 22, 24 or 26 and detecting formation of a complex between the acidic repeat protein or a peptide of the acidic repeat protein, if such is in the biological sample, and the antibody, wherein the presence of the complex indicates the presence of *Treponema pallidum*.

27. The method of claim 1, wherein the immunogenic peptide comprises the amino acid sequence as shown in SEQ ID NO: 20.

28. A kit for detecting *T. pallidum* in a biological sample using the method of claim 1, comprising an isolated acidic repeat protein or one or more isolated, immunogenic *Treponema pallidum* peptide of the acidic repeat protein, and instructions for carrying out the method of claim 1.

30. The method of claim 2, wherein the repeat region of the acidic repeat protein comprises the amino acid sequence set forth in SEQ ID NO: 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, or 18.

31. The method of claim 16, wherein the immunogenic peptide comprises a repeat region of the acidic repeat protein.